3H8175

RECEIVED
OPPT CBIC

2012 AUG 28 AM 9:08

[redacted]

August 22, 2012

Via FedEx / Signature Required

8EHQ-12-18792

[redacted]

TSCA Confidential Business Information Center (7407M)
EPA East Building – Room 6428
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC, 20460-0001
Phone: 202-564-8940

88120000335/S

Company Sanitized

Attn.: TSCA Section 8(e)

Re: TSCA Section 8(e) Submission for the Chemical Substance identified as Diphenyliodonium-2-Carboxylate Monohydrate (CAS Registry Number 96195-89-0)

Dear Sir/Madam:

[redacted] ("[redacted]" or the "Company") submits the enclosed letter report under Section 8(e) of the Toxic Substances Control Act ("TSCA"). This information is being provided in order to inform the U.S. Environmental Protection Agency ("EPA" or the "Agency") of the results from a GLP acute oral toxicity test on the chemical substance identified as Diphenyliodonium-2-Carboxylate Monohydrate ('the substance") (CAS Registry Number 96195-89-0):

Acute oral toxicity study of DPI[1] *in rats*

This study was sponsored by [redacted]. Presented here is the translated English version of the letter report based on the original Japanese document. The Company understands that a full test report was issued by the testing facility and furnished to [redacted]. [redacted], however, has only been provided with a copy of the translated English version of the letter report. If EPA wishes to receive the full test report, [redacted] will attempt to obtain a copy.

Company Sanitized

[1] Diphenyliodonium-2-Carboxylate Monohydrate. It is a hydrous form of diphenyliodium-2-caroxylate (CAS No. 1488-42-2)

The Company is submitting this information based on the sole finding of ataxic gait observed in the 2000mg/kg dose group. This submission is being made based on our understanding that no one has reported this effect before. The Company has not made a determination as to whether a substantial risk of injury to human health or the environment is actually presented by this information. Rather, this information is submitted in order to ensure that the EPA Administrator is adequately informed of such information.

[redacted] has mainly imported [redacted] containing the substance [redacted], though this substance may be imported itself in the future as a basic ingredient of [redacted]. In either case, the substance will be used only by trained technical personnel under highly controlled clean-room conditions that essentially eliminate the potential for human exposure to the substance. Furthermore, if the substance is, as a basic ingredient, imported, the material safety data sheet (MSDS) describing the results of this acute oral toxicity study will be updated.

Finally, [redacted] claims certain information in this TSCA Section 8(e) submission as confidential business information (CBI). In particular, CBI claims are being made for : (1) the company identity and the identity of its parent company, (2) the identity of the person signing the Section 8(e) submission, (3) the product in which the substance is contained, (4) the concentration of the substance in such product, and (5) the intended use of the product. In addition, [redacted] also provides herein substantiation concerning these CBI claims.

If there are any questions regarding this submission, please contact the undersigned at [redacted] Thank you for your consideration in this matter.

Sincerely,

[redacted]

Enclosures:

- Study summary – Acute oral toxicity study of DPI in rats (*confidential* version)
- Study summary – Acute oral toxicity study of DPI in rats (*sanitized* version)

The test result below was provided by [redacted]

TEST SUBSTANCE: DPI (Lot.ACINJ)

REFFERENCE No.: A3047

TITLE: Acute oral toxicity study of DPI in rats

[CONTENTS]

Ataxic gait was observed in the 2000 mg/kg group.
We judged this report need to be submitted, based on the criteria of clinical sings for the TSCA 8(e).

[COMMENTS]

METHODS:

Animals: Crl:CD(SD) rats, female, 7 weeks old, 5 animals
Body weight range at the initiation of exposure: 166 – 180 g
Route of administration: Oral
Dose levels: 2000 mg/kg
Dosing volume: 10 mL/kg
Vehicle: 0.5% MC
Observation items: Clinical signs, Body weight, Gross pathology
Observation period: 14 days

RESULTS:

LD_{50} value: >2000 mg/kg (female)
Mortality: No death was observed in the 2000 mg/kg group.
Clinical signs: Except for the clinical sign described above, irregular respiration and smudge (perinasal area and vulva).
Body Weight: No treatment-related change was observed in the 2000 mg/kg group.
Gross pathology : No treatment-related change was observed in the 2000 mg/kg group.

(Completed)